

ABSTRACT OF THE INVENTION

The invention comprises systems, methods and a computerized data management device for creating and using data relating to a medical or non-medical product or device to enhance the safety of the product or device. A vast amount of data regarding adverse events associated with a particular product or device is analyzed to identify new essential adverse events associated with the product or device. At least one database of new essential adverse event information is created and utilized, and new characteristics of or uses for the product or device related to the new essential adverse event information are determined. Adverse event information is gathered for a large number of population sub-groups. The system may also be programmed to incorporate the information into intellectual property and contract documents. Manufacturers and/ or distributors can include the proprietary information in consumer safety information, which accompanies the product or device, or which is provided to patients, users, consumers and the like, or in the case of certain medical products or devices, to prescribers of those products or devices. The system and methods also provide for commercializing the essential adverse event information.